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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,339	03/12/2002	Peter Jungblut	028622-0108	1997

7590 03/01/2005

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EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 03/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,339

Applicant(s)

JUNGBLUT ET AL.

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19November2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-45 and 48-68 is/are pending in the application.
- 4a) Of the above claim(s) 27-43, 48-50 54-57, 64-68 drawn to protein is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44,45 and 48-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 27-45 and 48-68 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' Response to Office Action, received 19 November 2004, is acknowledged.

Claims 27, 44, 48, and 54 have been amended. New claims 63-68 have been added.

The amendment of claim 51 is improper because the deleted material "of claim 27" has not been properly indicated.

2. Claims 27-45 and 48-68 are pending. Claims 27-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Also, claims 48-50 and 54-57 and newly added claims 64, 65, 67 and 68 remain drawn to nonelected inventions, i.e., protein composition and methods of use of said proteins, and as such that portion of the claims drawn to the nonelected inventions also remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

3. Claims 44, 45, and 48-68 drawn solely to DNA and methods of use are under consideration.

Restriction Requirement

4. Applicants request that the examiner withdraw the restriction requirement at least as to claims 27-45 and 48-57 of Groups I and II and examiner those claims in a single application based upon applicants' arguments that there is unity of invention according to PCT Rule 13.2.

The examiner has considered applicants' argument, but does not find it persuasive for the reasoning put forth in the original restriction requirement, i.e., Groups I and II are drawn to two different special technical features, nucleic acids and proteins, which when utilized in methods for immunization or diagnosis are utilized in patentably distinct steps utilizing different reagents. Thus, the special technical features are distinct.

Rejections Withdrawn

5. The rejection of claims 44, 45, and 48-62 under 35 U.S.C. 112, first paragraph, scope of enablement for isolation and use of nucleic acid molecules coding for proteins which are differentially expressed in virulent *Mycobacterium* compared to avirulent strains of *Mycobacterium*, is withdrawn in light of applicants' argument.

Applicants argue that the specification clearly identifies proteins which are differentially expressed and that the cited references provide sufficient information to identify the corresponding encoding nucleic acid sequences.

Rejections Maintained

6. The rejection of claims 48-50 and 54-57 and now newly added claims 64, 65, , 67 and 68 under 35 U.S.C. 112, second paragraph, indefiniteness for being drawn to nonelected inventions, is maintained.

Applicants argue that the amendment of the claims fulfill the Unity of Invention requirement and therefore claims drawn to proteins should no longer be considered a separate invention and indefinite.

The examiner has considered applicants' argument, but does not find it persuasive for the reasons put forth in the original rejection. In addition, the claims are drawn to two different special technical features, nucleic acids and proteins, which when utilized in methods for immunization or diagnosis are utilized in patentably distinct steps utilizing different reagents. Thus, the special technical features are distinct.

New added claims 64, 65, , 67 and 68 are also drawn to nonelected inventions and therefore would have been included in the original rejection.

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7. The rejection of claim 51 under 35 U.S.C. 112, second paragraph, indefinite for depending from a nonelected claim 27, is maintained for reasons of record.

Applicants argue that claim 51 has been amended to remove the reference to claim 27.

The examiner has considered applicants' argument, but does not find it persuasive because claim 27 has been improperly amended. New material has been properly added to the claim, but deletion of "of claim 27" is improper because the deleted material has not been so indicated by the required notation in the claim.

8. The rejection of claims 49, 51, 52, and 54 and newly added claims 65 and 68 under 35 U.S.C. 112, first paragraph, scope of enablement for vaccines, is maintained.

Applicants argue that the Declaration of Prof. Kaufmann demonstrates that the specification is enabling for vaccines. Prof. Kaufmann states that DNA encoding whole Rv0068 and whole Rv3407 was protective in mice challenged with *M. tuberculosis*.

The examiner has considered applicants' argument, but does not find it persuasive except for nucleic acid sequences which encode whole Rv0068 and Rv3407 as vaccines against one species of *Mycobacterium*, i.e., *M. tuberculosis*. The Declaration of Prof. Kaufmann does not address the scope of the claims, i.e., DNA encoding fragments or fusion proteins of all of the listed proteins, as being vaccines against any/all virulent strains of the genus *Mycobacterium*.

New added claims 65 and 68 are also drawn to vaccine and therefore would have been included in the original rejection.

9. The rejection of claims 44, 45, 48-62 and newly added claims 63-68 under 35 U.S.C. 112, first paragraph, scope of enablement for identification of proteins by comparison of any/all

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other virulent strains of *Mycobacterium* to any/all other avirulent strains of *Mycobacterium* is maintained.

Applicants argue that the amendment of the claims and the teachings in the specification obviate the rejection.

The examiner has considered applicants' argument, but does not find it persuasive for the reasons put forth in the original rejection. The specification teaches only one comparison, between *M. tuberculosis* and *M. bovis* BCG and identifies specific *M. tuberculosis* proteins labeled Rv----- . The specification does not identify any other proteins nor nucleic acid sequences encoding them in by comparing any other *Mycobacterium* species or strains.

New Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 44, 45, 48, 49,50, 51, 52, 53, 54, 55, 56, 57, 58, and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Newly amended claims 44, 48, and 51 now recite specific proteins of *M. tuberculosis* which are identified by comparison of any/all virulent *Mycobacterium* compared to any/all avirulent *Mycobacterium*.

It is unclear how one identifies a specific *M. tuberculosis* protein by comparison of, e.g., *M. scrofulaceum* with *M. marinum*.

Conclusion

12. No claims are allowed.

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13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

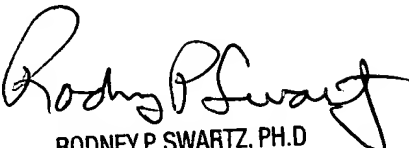
If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER

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February 22, 2005